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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/461,829	12/15/1999	ROBERT-JAN ENZERINK	265280-64723	4338

7590 10/30/2002

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 10/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/461,829

Applicant(s)

ENZERINK ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,35,36,38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,35,36,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 35, 36, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire (5562669) in view of Dumican et al. (4987665). McGuire discloses that allografts can be used as replacement ligaments, col. 6, lines 32-42. McGuire discloses to have sutures attached at a proximal end and distal end and include using semitendinosis and gracilis tendons, col. 5, lines 1-11 and col. 6, lines 60-61. McGuire also discloses the sutures are attached **prior to** implantation to aid in insertion, col. 5, lines 54-62. McGuire additionally discloses preserving grafts that are used for future ligament replacement procedures, col. 6, lines 34-36. It is inherent the preserved graft would be sterilized and packaged. The graft can be a bundle of strands, col. 6, lines 60-61. McGuire additionally discloses that fixation devices are used in "kits" for ligament repair, col. 5, lines 17-22. Because the individual components of applicant's claimed kit *for ligaments* are known in the prior art, it can be construed that any type of combination of these components available at the same time form a "kit". However, McGuire does not disclose a package or kit with sutures attached to the graft prior to sterilizing and packaging. Dumican teach grafts are packaged and sterilized with pre-attached sutures, col. 11, lines 34-41. It would have been obvious to one of ordinary skill in the art to have the pre-attached sutures on the graft ligament of McGuire

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and have the sutures already attached prior to packaging and sterilizing as taught by Dumican in order to save valuable time for the patient and reduce the surgery time required for placing the sutures in the ligament during the surgery. Also, it would be an advantage to attach the sutures and graft together prior to packaging, in that it reduces extra packaging if they were separate.

Claims 5, 6, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire '669 in view of Dumican '665 and further in view of Schmieding '561. McGuire as modified by Dumican is explained supra. However, McGuire in view of Dumican do not disclose the use of long strand sutures and various lengths of ligaments.

Schmieding teaches that long strand sutures are placed on the graft to aid in placement in a patient, col. 5, lines 25-32. Schmieding also teaches to use various lengths for ligament repairs, col. 4, lines 56-66. It would have been obvious to one of ordinary skill in the art to provide various lengths of ligaments and use long sutures as taught by Schmieding for the graft of McGuire as modified by Dumican in order to provide the proper length necessary for the patient and have sufficient suture to secure it in place.

Claims 1-4, 35, 36, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire '669 in view of Li et al. (5715942). McGuire is explained supra. However, McGuire does not disclose pre-attached sutures with the graft in sterile packaging. Li et al. teach of a medical device used in surgery that has the sutures pre-attached to the device and provided in sterile packaging, see abstract. It would have been obvious to one of ordinary skill in the art to move the step of pre-attaching the sutures to the graft prior to packaging as taught by Li et al. instead of just

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pre-attaching the sutures to the McGuire graft prior to implanting such that the graft is ready to be implanted immediately once opened from the package.

Claims 5, 6, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire '669 in view of Li et al. '942 and further in view of Schmieding '561. McGuire as modified by Li et al. is explained supra. However, McGuire in view of Li do not disclose the use of long strand sutures and various lengths of ligaments. Schmieding teaches that long strand sutures are placed on the graft to aid in placement in a patient, col. 5, lines 25-32. Schmieding also teaches to use various lengths for ligament repairs, col. 4, lines 56-66. It would have been obvious to one of ordinary skill in the art to provide various lengths of ligaments and use long sutures as taught by Schmieding for the graft of McGuire as modified by Li in order to provide the proper length necessary for the patient and have sufficient suture to secure it in place.

Response to Arguments

Applicant's arguments with respect to claims 1 and 35 have been considered but are moot in view of the new ground(s) of rejection. Regarding the combination of McGuire and Dumican it is noted that Dumican does teach grafts and has suture material attached to the graft. However, the rejection of McGuire in view of Dumican apparently was not conveyed properly in reading the remarks by Applicant's representative. It is the examiner's position that McGuire already teaches attaching sutures to proximal and distal ends of the graft and this is done prior to implanting or surgery. The teaching that the examiner is relying on from Dumican is that a graft is

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sterilized and has suture material in the same package. Thus one of ordinary skill would look to combine these because McGuire is silent as to whether the suture and graft are in the same package, but does mention packaging as cited above. Thus, it would be an advantage to attach the sutures and graft together prior to packaging, in that it reduces extra packaging if they were separate.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino
October 24, 2002

Brian E. Pellegrino



Bruce Snow
Primary Examiner
TC 3700, AU 3738